

EN (English)



## PVA Sponge Spears

### DEVICE DESCRIPTION

GAMMA sterilized compressed PVA sponge spears mounted on PP sticks packed in peel open pouches.

### INTENDED USE/ INDICATION FOR USE

A sterile compressed PVA sponge spear is used to absorb excess fluids from the corneal / scleral surface or to manipulate tissue during an ophthalmic surgical procedure. A PVA sponge is particularly preferred in the LASIK laser surgery due to a very soft cell structure when wet.

### MATERIALS USED

PVA, K-resin

### TARGET AGE GROUP

Can be used for all age groups.

### INTENDED USER

Any of the registered medical doctor/medical professionals.

### DURATION OF USE

Transient Use (Less than 60 Minutes).

### STORAGE CONDITIONS

Store at specified temperature and relative humidity (Temperature in between 10°C to 30°C and relative humidity in between 45% to 65%).

### CONTRAINDICATIONS

The device should not be used in patients who show hypersensitivity to any of the materials used in Manufacturing of the device.

### HOW SUPPLIED

PVA sponge spears are supplied sterile, in a pack of 5. Fifty (50) such pouches are enclosed within an outer printed box. The overall packing contains PVA sponge spears and medical literature insert, in an outer enclosing box, with external identification stickers.

### CAUTION/ WARNING

- Do not use if package is damaged and consult instructions for use.
- The used PVA Sponge Spears might not have sufficient soaking capacity and may not comply with the claim.

information, your reference and reason for return. Please contact your local distributor office regarding product return/exchange.

### REPORTING

Adverse events and/or potentially sight-threatening complications that may reasonably be regarded as product related and that were not previously expected

### EXPLICATION OF SYMBOLS:

Symbol	Meaning
	Caution
	Manufacturer
	Date and Country of Manufacture
	Consult instructions for use
	Keep away from sunlight
	Medical Device
	Do not use hook
	This side up
	Temperature Limit
	Humidity Limitation
	Keep Out of reach of children

- The PVA Sponge Spears gets deformed after wetting. The used PVA Sponge Spears might not be in a position to be used again due to this deformed shape.
- Re-use of device may lead to microbial contamination due to presence of Pseudomonas.
- Contagious and communicable diseases such as HIV, Hepatitis, contagious diseases/communicable disease/undue diseases etc.
- Only qualified medical practitioners should use the device as per the intended use.
- Do not reuse the device.
- Keep out of reach of children.
- The used PVA sponge spears and pouch should be disposed of in compliance with the local regulatory requirements.
- For External use only.
- Do not use the device after sterility expiry date.
- Do not use the device if the sterilized package is open or damaged.
- Mishandling or improper transport can cause damage to the device or packaging.



### PRECAUTIONS

- Ensure before use that product/packaging is not tampered or damaged.
- When handling the product care should be taken to avoid damage from handling.

### DIRECTION FOR USE

- Check the package sealing integrity to ensure sterility.
- Open the pouch and take out the spear.
- The tip of the spear is gently placed on the area from which the fluid is to be absorbed.
- The sponge swells up on absorbing the fluid and ceases to absorb any more fluid after a point. The used sponge spear should not be reused and put back into the pouch and disposed off with other waste for incineration.
- In case the PVA spear is to be used for corneal tissue manipulation, dip the tip of the sponge in saline solution for few seconds. This will make the PVA sponge very soft and suitable for corneal tissue manipulation.

### EXPIRATION DATE

The expiration date of the product is the sterility expiration date. The product should not be used after the indicated sterility expiration date, the shelf life for sterile products is recommended to 5 years from the date of sterilization.

### RETURN OF DAMAGED PRODUCT

Return the product in its original packing identified by the batch number, purchase

in nature, severity or incidence must be report to Madhu Instruments Pvt. Ltd.

### DISPOSAL OF THE USED DEVICE

The used device should be disposed off in compliance with applicable local, state and country's laws and regulations.

Symbol	Meaning
	Handle with care
	Maximum stacking
	Batch Code
	Use by date
	Do not use if package is damaged and consult instructions for use
	Do not re-use
	Single Sterile Barrier System, sterilized using irradiation
	Single Sterile Barrier System with protective packaging outside, sterilized using irradiation
	Do not re-sterilize
	Catalogue Number
	Unique device identifier

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